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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61N 7/00	A1	(11) International Publication Number: WO 00/21612 (43) International Publication Date: 20 April 2000 (20.04.00)
<p>(21) International Application Number: PCT/IL99/00533</p> <p>(22) International Filing Date: 8 October 1999 (08.10.99)</p> <p>(30) Priority Data: 126505 9 October 1998 (09.10.98) IL</p> <p>(71) Applicants (for all designated States except US): ULTRA CURE LTD. [IL/IL]; Chamamat Hatechnion, Science Park Technion, P.O. Box 212, 36601 Neshet (IL). SEGAL, Emanuel [IL/IL]; Hagalil Street 45, 32686 Haifa (IL).</p> <p>(72) Inventors; and (75) Inventors/Applicants (for US only): IGER, Yoni [IL/IL]; Zrubavel Street 15, 34671 Haifa (IL). SHALHEVET, David [IL/IL]; P.O. Box 658, 25147 Kfar Vradim (IL). ELMAN, Dmitry [IL/IL]; Karkom Street 7/1, 21053 Maalot (IL).</p> <p>(74) Agent: REINHOLD COHN AND PARTNERS; P.O. Box 4060, 61040 Tel Aviv (IL).</p>		<p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report.</i></p>
<p>(54) Title: A METHOD AND DEVICE FOR HAIR REMOVAL</p> <p>(57) Abstract</p> <p>The invention concerns various methods for removal of hair utilizing ultrasound and devices and systems for use in connection with these methods.</p> <div data-bbox="665 1134 1299 1827"> </div>		

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A METHOD AND DEVICE FOR HAIR REMOVAL

FIELD OF THE INVENTION

The present invention concerns ultrasonic methods, processes and devices for hair removal.

BACKGROUND OF THE INVENTION

5 Hair removal is carried out mostly for cosmetic purposes, in order to remove undesired hair from different skin regions of the body.

Numerous methods and devices have been developed for temporary or permanent removal of undesired hair. The main methods for hair removal currently used include methods based on hair cutting such as shaving, methods
10 based on plucking out hair from its root either by mechanical devices or by use of sticky substances such as wax, methods for chemically dissolving hair such as chemicals used for depilation and methods for the supposed permanent destruction of hair roots such as by use of electrical currents (electrolysis), or laser beams (thermolysis).

15 Cutting of hair, such as by shaving, affects only the part of the hair shaft that is outside the skin. The living part of the hair, in the hair papillae continues to grow and therefore the hair removal effect is short lasting.

Waxing takes out most of the hair adhered to wax and tears apart the hair or disconnects the hair from its papillae. The papillae itself remains at least
20 partially vital and the living cells will establish a new hair germination zone subsequently leading to renewed hair growth. Waxing can leave hair papillae and skin pores sore and open to infections, and cannot be used over varicose veins, moles or warts.

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Depilation by chemical agents is carried out by using gels or creams that contain highly alkaline chemicals, usually calcium thioglycolate, that dissolve the protein structure of the hair, leading to its separation from the papillae. The concentration of the chemical is kept as low as possible so as to allow hair lysis, while avoiding skin irritation. The effects of depilation by chemical substances is also relatively short termed and is occasionally accompanied by skin irritation.

Electrolysis is performed by transmitting a direct current to the hair root in order to form hydroxyl ions that electrochemically destroy the germinative cells of the hair follicles. Thermolysis is performed using high frequency currents to heat the water of the hair follicle and electrocoagulate the germinative hair cells (Richards RN and Meharg GE Electrolysis: observations from 13 years and 140,000 hours of experience. *J. Am. Acad. Dermatol.* **33**:662-666, (1995)). Both electro- and thermo-lysis are considered permanent methods for hair removal, even though the regrowth after treatment is 15-50%. These methods are carried out by using a needle inserted into the hair follicle, a rather painful and infection-prone process. The results of this procedure are heavily dependent on the skill of the person operating the electrolysis or thermolysis devices, and unskilled treatment may cause pigmentation, scarring of the skin, infection and small electrical shocks.

Laser hair removal is carried out by transmitting a focused laser beam (USA Pat No 5632741), optionally with the aid of previously applied black colored solution to increase energy absorbance, to the hair follicle (US Patent No. 5752948). The hair, or the dark solution, absorbs the laser energy and as a result its temperature increases leading to destruction of the follicle (Lask G, *et al.*, Laser assisted hair removal by selective photothermolysis; Preliminary results. *Dermatol. Surg.* **23**: 737-739, (1997)). This method depends on the hair color and achieves acceptable results with dark hair and light skin. Persons having dark skins or light hair are not ideal candidates to hair removal by laser energy hair removal. Even optimal candidates suffer from 40-80% hair regrowth

after 12 weeks and has further side effects such as redness, skin pigmentation and even scaring.

It is known that is a poor conductor of electricity (hair resistance has been calculated at: $R_{\text{(resistance)}} = 82.6 \times 10^9$ ohms (Human Hair Conductivity Test, Fischer)) and light hair is also a bad absorber of light energy. Against this, hair, as other dense fibers, is a relatively good conductor of sound including ultrasound, regardless of its or the skin color.

GLOSSARY

10 The following terms will be used throughout the description:

“*Focused Ultrasonic Beam*”- a beam whose area gets progressively smaller and its intensity progressively higher as the beam is further away from the transmitter until it reaches the focal point. Further away from the focal point, the beam width increases again. The “acoustic focal point” is determined as to the region of the beam where the area is smallest and the density of the energy is highest.

20 “*Ultrasonic Longitudinal Waves*” - A manner of propagation of ultrasound through solids or liquids is due to the compressions and decompression along the direction of wave propagation, leading to compression or tension stress. The movement of the particles in these waves is essentially parallel to the direction of the propagation of the waves.

25 “*Ultrasonic Shear Waves*” - Another manner of propagation of ultrasound through solids, is a wave of shear stress along the waves’ propagation. Its velocity is smaller than that of the longitudinal wave. Shear waves are created all over the irradiated solid, but their effects are noticeable in particular in the interfaces between different types of solid materials causing shear stress. The movement of the particles in the solid substance with shear waves is essentially perpendicular to the propagation of the wave.

“*Cavitation*” is the effect of the rapid creation of gas bubbles in liquid due to ultrasonic irradiate, pulsation of these bubbles and their final collapse. This phenomenon is caused by rapid transduction from super-pressure to sub-pressure which the ultrasonic force produces on the bubbles. The bubbles are created
5 around “*nuclei of cavitation*” which may be particles (for example pre-existing gas bubbles in the liquids), non-homogeneity in the liquid and the like.

“*Resonance*” – A phenomenon where the ultrasonic field acts on a substance or body at the self frequency of to substance/body. At such a condition, a relatively
10 low ultrasonic field can impact high energy. This phenomenon is amplified for example when standing waves are created i.e. when the reflected wave has the same phase and opposite direction as the incident wave. Resonance may be created by several types of ultrasonic waves, such as shear waves or longitudinal waves. Since the velocity of shear waves under the same conditions is about half
15 of that of longitudinal waves, the resonance frequency created by theses waves will also be about half.

“*Resonator*” - A device having a size (i.e. geometrical factors) enabling creation of resonance effect, namely the effect of incident waves is amplified b y the
20 subsequent incident waves.

“*Torsion waves*” – A manner of propagation of ultrasound through solids where particle movement is circular.

25 “*Bending waves*” – A manner of propagation of ultrasound through solid as flexural wave.

SUMMARY OF THE INVENTION

The present invention concerns novel cosmetic methods, devices and systems used therefor, allowing the removal of undesired hair. This, in accordance with the invention is achieved by utilizing ultrasonic forces. Thus the present invention concerns a cosmetic method for removal of hair from a desired body zone using ultrasonic force.

The term "*hair*" in the context of the present invention refers not only to the hair shaft but also to hair root, the hair follicle, the hair papillae and the blood supply to the hair.

10 The term "*removal*" in the context of the present invention refers to destruction of any of the above components, to the cease, inhibition or to the decrease in proliferation rate of cells in those components leading to cessation or to reduced rate of hair growth for example as manifested by force-free epilation.

In accordance with a first aspect of the invention termed "*focal beam*
15 *epilation*", the present invention provides a method and device for the removal of hair using a focused ultrasonic beam. The focused ultrasonic assembly is applied for example in accordance with co-pending Patent Application PCT/IL97/00406 incorporated herein by reference. Briefly, this application refers to an ultrasonic system having an ultrasound transmitter element capable of producing a focused
20 ultrasonic beam, the latter referring to a beam which area is becoming progressively smaller, and its intensity per area progressively higher as the beam is further away from the ultrasound transmitter. At the acoustic focal point the area of the beam is smallest and the intensity of the beam is the highest. Such a beam is produced by an ultrasonic transmitter and focusing means, such as acoustic lenses
25 or focusing transducer. The system of this application also comprises a container holding a liquid medium coupled at one end to the ultrasound transmitter element for guiding the focused ultrasonic beam to the desired hair removal region of the

skin, the container or "*the guide*" having such parameter that the ultrasound beam propagates therein without bouncing on the side walls of the container.

The focused beam is preferably produced with such parameters so that most of the energy is absorbed by the dense hair and not by the skin. The ultrasonic beam
5 can penetrate through the skin layers above the hair papillae, without destroying said skin layers, and only at the focal point, or the regions close to the focal point, is the ultrasonic energy high enough in order to destroy living cells, and thus, while the skin above and around the papillae or blood supply to the hair remains essentially intact, the papillae or blood supply is destroyed by ultrasonic force.
10 Areas above the focal point are essentially not effected..

An example of ultrasonic parameters to perform this aspect are as follows:

Frequency: 20 kHz to 25 MHz, preferably 1 MHz to 10 MHz, most preferably 3 MHz to 7 MHz.

Intensity: 5 W/cm^2 to 750 W/cm^2 , preferably 30 W/cm^2 to 500 W/cm^2 , most
15 preferably 100 W/cm^2 to 300 W/cm^2

Duration: 1 millisecond to 10 seconds, preferably 0.01 second to 2 seconds, most preferably 0.1 second to 0.5 second.

In accordance with a second aspect of the invention, termed "*hair wave-guide epilation*" the present invention provides a method for removal of hair,
20 wherein the ultrasonic energy is delivered via the hair shaft itself, which serves as a wave guide. According to this option, the ultrasonic beam may be in the form of longitudinal waves, sheer waves, torsion or bending waves and is targetically transmitted via the hair shaft into the hair papillae. The delivery of these energy waves through the hair shaft into deeper, living parts of the hair, causes sufficient
25 mechanical distortion, vibration, bending and torsion-created torque, or thermal elevation for the destruction of hair notably the hair root follicle and/or papillae. The procedure can be carried out on untreated skin, as well as skin and hair pretreated for example by drying and trimming of the hair. Hair serves best as a wave guide when it is dry so that during treatment hair should preferably be as dry

as possible. In order to reduce energy attenuation along hair length, the hair should preferably be as short as possible and should preferably be trimmed for example by shaving prior to treatment. Dry hair also minimizes leakage of energy from the hair to the surrounding skin.

5 There are several considerations for conductivity of emitted ultrasonic wave via hair: geometrical parameters of the hair such as (length and width), the angle between the hair and the ultrasonic probe, the air gap between the probe and the skin surface, are all important parameters to be taken into consideration in connection with the yield of the process. For example, for longitudinal and
10 shear wave guiding, hair should be preferably cut, to reduce attenuation along the hair shaft since the longer the hair the greater the attenuation. The placement of the hair in respect to the emitter of energy itself should provide required angle between transducer surface and hair surface, preferably the transducer should be perpendicular to the hair so that the wave propagates in the hair itself without
15 bouncing off the hair wall and losing energy.

Another way to transfer the ultrasonic energy through the hair is to use the hair as an $n\lambda/2$ horn (to achieve maximal velocity at the root or papillae) or $n\lambda$ horn (to achieve maximal intensity at the desired site). This means to cut the hair so that the length of the hair will be an integer number of half wavelengths and
20 therefore the amplitude of the signal, and the desired effect, at the hair root will be maximized. For example if the wave length is 3mm the horn will be multiples of this number (3,6,9 etc.) and the hair will be trimmed to have similar sizes

One way to transfer the energy through the hair is to ensure that the wavelength of the ultrasonic beam should be about the same order of magnitude
25 of the hair dimensions. The diameter of the hair is about $70\mu\text{m}$ and velocity of sound in the hair under certain conditions is $c=1700\text{m/sec}$. For the longitudinal wave, the frequency to receive the maximum effect will be about 21MHz, while for shear waves or torsion waves having about half velocity, will be about 10.5MHz or less. The general calculation is based on $f=c/\lambda$ (f =freq., c =velocity,

λ =wave length), for hair of a diameter of a 100 microns the frequency of the longitudinal waves should preferably be 15 MHz.

For bending waves the frequency may be reduced to a frequency of about half of shear waves, for example to about 5MHz. Bending waves may be produced using a single transducer, preferably perpendicular to the hair, or two transducers either one above the other or one opposite the other.

The ultrasonic parameters to perform this aspect may be for example:
Frequency for longitudinal waves: 1 MHz to 50 MHz, preferably 10 MHz to 30 MHz, most preferably 15 MHz to 25 MHz.

- 10 The frequency depends on the specific hair diameter of the treated subject.
Frequency for shear or torsion waves- about half of the above. For bending waves- about 1 quarter of the above, for example:
Intensity: 0.5 W/cm² to 500 W/cm², preferably 3 W/cm² to 50 W/cm², most preferably 10 W/cm² to 20 W/cm²
15 Duration: 0.01 second to 10 minutes, preferably 1 second to 5 minutes, most preferably few seconds.

The damage and transfer of energy will be most efficient when the ultrasonic wave will be in resonance with the follicle and papilla. For the dimension of the follicle and papilla of 100 μ m, the frequency that will cause resonance will be about 17MHz for longitudinal waves, about 8MHz for shear waves and about 4MHz for bending waves. In resonance mode, because of the high efficiency, the intensity of the wave may be reduced. The present invention provides in accordance with a third aspect thereof a method for the destruction of at least one component of the hair, the hair root, hair follicle papillae or capillary blood supply to the hair, using cavitation. Therefore in accordance with a third aspect of the invention termed "*cavitation epilation*", the present invention provides a method and procedure for creating cavitation bubbles in the hair follicle, preferably at its inner side, for the destruction of at least one component of the hair follicle, root, papillae or blood supply.

The effect of cavitation may be achieved by the production of bubbles and their collapse which, due to mechanical disruption elevated temperature, pressure and micro-streaming that destructs the surrounding regions.

The effect of cavitation can be achieved also using oscillating cavitation bubbles where the desired damage to the tissue is achieved not by explosion of transient bubbles but by oscillation of stable ones. The stable oscillating bubbles produce heat having just a local thermal effect which leads to destruction by surrounding tissue. In distance of one bubble radius from the bubble itself, temperature gradient reduces about 90 times (for 1 MHz frequency and bubble of 10 μm radius). In case that the bubble is present on the cell membrane and most bubbles are on cell membrane or close to it since the space between the hair shaft and the follicle is about 10 microns, it produces enough heat to destroy the components of the tissue adjacent thereto. The factors affecting bubble wall temperature are T_0 -surrounding temperature, p_0 -acoustic pressure, ω_0 -resonant frequency for given bubble radius, K' - gas thermal conductivity and δ_{vis} , δ_{th} , δ_{tot} are energy dissipation for viscosity, temperature and total energy dissipation as shown in the formula:

$$T_b = T_0 + \frac{p_0^2}{2\rho_0\omega_0 K'} \frac{\delta_{vis} + \delta_{th}}{\delta_{tot}^2}$$

In order to estimate the temperature on the bubble wall the following equation was used:

$$T_b = T_0 + 8.12 \cdot 10^{-12} \cdot p_0^2,$$

acoustic pressure in dyn/cm^2 . For transducer of 1MHz, the acoustic pressure is about $1.8 \cdot 10^6 \text{ dyn/cm}^2$, so that temperature rising on the bubble wall is 26.6°C . If normal human temperature is 37°C , $T_b = 63.6^\circ\text{C}$. It's enough to damage cell structures when bubbles are oscillating for a period of time.

The cavitation depends on the ultrasonic parameters (intensity, frequency), material characteristics (surface tension, viscosity, density, vapor pressure) and bubble characteristics (volume, compressibility).

The ultrasonic parameters to the cavitational aspect of the invention may be, for example, as follows:

Frequency: 1 kHz to 5 MHz, preferably 10 kHz to 2 MHz, most preferably 100 kHz to 1 MHz.

Intensity: 0.3 W/cm^2 to 500 W/cm^2 , preferably 0.5 W/cm^2 to 50 W/cm^2 , most preferably 1 W/cm^2 to 10 W/cm^2

Duration: 0.01 second to 10 minutes, preferably 1 second to 5 minutes, most preferably less than 7 sec.

The present invention provides in accordance with a fourth aspect thereof a method for the destruction of at least one component of the hair, root, papillae or capillary blood supply to the hair, using ultrasound either to activate hair degenerative agents naturally present or externally administered to the hair papillae and/or to facilitate intrafollicular delivery of follicle degenerative agents. Therefore in accordance with a fourth aspect of the invention termed "*degenerative agents epilation*", the present invention provides a method and procedure for the active and/or delivery of different natural or artificial chemical degenerative agents into the hair follicle for altering the cell cycle of papillae, root or follicle cells, and for the destruction of at least one component of the hair, the hair root, hair follicle, papillae or capillary blood supply to the hair.

By one option this embodiment may take advantage of natural compounds of the skin which may be used to destroy hair, i.e. use compounds already present in the skin as degenerative agents.

For example, epilation can be performed by irradiating the skin surface using ultrasound of preferably high frequency so as to heat the desired zone with the hair with minimum penetration into deeper layers. The irradiation affects differentially the different components of the skin. For example whereas the bulk

of the skin is water having attenuation of 0.05 db/cm, the follicle is partially filled with sebum and is attached to the sebaceous gland. The sebum is actually fat having attenuation of 0.5 db/cm., i.e. ten times more than the skin. Therefore when irradiated, the sebum will accumulate heat and elevate its temperature about
5 10 times more than the surrounding tissue, causing localized lysis and destructure of the living part of the hair. Tweezers can be used to finally force free epilate the hair after the process.

According to yet another example, the intrafollicular delivery of follicle degenerative agents is facilitated by ultrasound. The delivery itself is a modified
10 version of the method stipulated in co-pending PCT/IL 97/00405. In accordance to this aspect the tissue surface is exposed to a first irradiated stimulus having such parameters as to enlarge the space between the hair shaft and the follicle itself and to remove from said space wax (fat) and debris, without causing any irreversible damage; and within a time period where a substantial portion of said
15 openings remain open, a second driving ultrasound stimulus is administered in the presence of at least one follicle-degenerative agent. Since the follicle is initially at least partially opened, and since it is desired to deliver intrafollicular the degenerative substance to a depth of 2-4 mm in the partially empty follicle, two pulses are used in subsequent intervals i.e., opening pulse, driving pulse,
20 opening pulse, driving pulse, etc. The opening pulse is at generally low frequencies, preferably 100 kHz- 1 MHz. The driving pulse is of higher frequency, preferably 1-10 MHz. The duration of both pulses is preferably several seconds and intensity of several w/cm^2 .

After the delivery of the degenerative agent to the follicle, the skin is
25 wiped to remove remnants of the compound from the skin surface itself and the ultrasound is used to activate the degenerative agent.

The degenerative agent itself used to cause the desired epilation effect can be of the following groups: sonosensitizable agents capable of undergoing exothermic reactions upon ultrasonic irradiation or exposure to light, such as

gallium porphyrins, dimethylsulfoxide, dimethylformal and adramycin, NaN_3 , nitrocellulose and the like according to co pending PCT/IL98/00203 of the inventors, optionally with helper agents used to facilitate the destructive effect such as O_2 , chloride, kalium permanganate and the like, capable of contributing
5 to the effect, for example, by the releasing of radicals or other oxidative moieties. Examples of degenerative compounds which act by mechanisms other than oxidative or exothermic mechanisms are: oil that causes pore clogging and malnutrition of the hair root thus facilitating destruction of hair roots by heat; natural substances capable of affecting the cell cycle of the root, papillae or
10 blood vessel cell, including cytokines such as epidermal growth factors or tumor necrosis factors, or Interleukin-1 capable of shifting the growth cycle from the anagen to the catagen phase (the latter phase is the phase where the hair separates from its root); androgen hormones in particular dihydrotestosterone or 5-alpha-reductase that converts testosterone to its active form
15 dihydrotestosterone. The latter compete for a place on the hair follicle's receptor sites and when succeeded start shrinking the follicle and root death in different body zones.

The present invention provides in accordance with a fifth aspect thereof a method for the detachment and destruction of at least one component of the hair,
20 hair follicle, hair root, papillae or capillary blood supply to the plaque, using stretching and relaxation effects of resonance produced by ultrasonic energy in a resonator. Therefore in accordance with a fifth aspect of the invention termed "*resonator epilation*", the present invention provides a method and device for stretching and relaxing hair by transmitting an ultrasonic resonance energy which
25 matches the natural resonance of a resonator so as to cause fatigue effects in the hair follicle leading to the detachment and destruction of at least one component of the hair, hair root, hair follicle, papillae or capillary blood supply. The parameters for this aspect are exemplified in the Detailed Description of the Invention.

The present provides in accordance with a sixth aspect thereof a method for the destruction of the blood supply to the hair, using aggregation of blood cells. Therefore in accordance with a sixth aspect of the invention termed "aggregational epilation", the present invention provides a method and device
5 for causing aggregation of blood cells in the papillae blood vessel for hampering papillary blood supply to the hair, thus causing cessation or substantial reduction of supply of nutrients to the hair root and hair papillae leading to the detachment of hair due to the destruction of the hair root or papillae.

Aggregation is created when the wave is transmitted in aquatic medium
10 containing particles. It is created (among other factors) due to Bernoulli attraction force formed between particles caused by acoustic streaming, and due to disturbance of the oscillating movements of particles caused by the movement of the liquid in the acoustic field. The minimal intensity to create aggregation depends on particles size, density of liquid and density of particles according to
15 the following non-limiting equation: $I=3.7[\rho_0 / (\rho-\rho_0)]^2/a^3$ where I is intensity, ρ is density of particles, ρ_0 is density of solution and a is diameter of particles. Since blood is dense solutions having relatively large size of particles and running in relatively narrow capillaries, the intensities to create aggregation are relatively low at the order of mW.

20 The ultrasonic parameters to perform this aspect may be as follows:
Frequency for longitudinal waves: 10 kHz to 15 MHz, preferably 500 kHz to 10 MHz, most preferably 1 MHz to 5 MHz.
Intensity: 0.1 W/cm^2 to 50 W/cm^2 , preferably 0.5 W/cm^2 to 10 W/cm^2 , most preferably 1 W/cm^2 to 3 W/cm^2
25 Duration: 1 second to 10 minutes, preferably 10 seconds to 5 minutes, most preferably 30 seconds to 2 minutes. It should be noted that aggregation can be carried out with the hair serving as a hair guide and/or by direct irradiation through the skin directly.

The different aspects of hair removal may be carried out separately or in combination. For example focal beam epilation is suitable for removal of hair in non-sensitive skin regions such as the legs. Hair-guide epilation is suitable for treatment of sensitive regions such as the face. Cavitation epilation after
5 mechanical hair removal.

The present invention further concerns devices and systems for use in any of the above methods. The system is composed of wave signal generator attached to an amplifier and appropriate transducer and attachment devices. For focal beam epilation focusing means such as acoustic lenses should be supplied as well
10 as a conical wave guide. For hair-guide epilation means for holding the hair should be supplied. For resonator epilation a resonator should be supplied. For cavitation epilation and epilation with degenerative agents the system should contain components for supplying the cavitation helper agents or the degenerative agents to the skin.

15

BRIEF DESCRIPTION OF THE DRAWINGS

In order to understand the invention and to see how it may be carried out in practice, a preferred embodiment will now be described, by way of non-limiting example only, with reference to the accompanying drawings, in which:

20 Fig. 1 shows a schematic drawing of an epilation device using focused ultrasonic beam;

Fig. 2 shows a schematic drawing of transducer cover used to grasp a hair shaft end for epilation and using the hair shaft as wave-guide;

Fig. 3 shows a schematic drawing of transducer used for epilation using
25 bending wave where Fig. 3a shows a schematic drawing with two transducers used to remove hair and Fig. 3b shows a schematic drawing with one transducer. Fig. 3c shows schematically the effect achieved by ultrasonic irradiation on hair when leading to its distortion and eventual breaking;

Fig. 4 shows a schematic drawing of cavitation effect caused by ultrasonic irradiation in the hair follicle around the hair shaft;

Fig. 5 shows a schematic drawing of destruction of an empty hair papillae with cavitation after hair was previously removed therefrom (for example, by plucking) where the bubbles are created in the empty hair follicle;

Fig. 6 shows a schematic drawing of agglutination of blood cells in the blood capillaries around the hair root leading to cessation of blood and nutrient supply to the root;

Fig. 7A shows a schematic drawing of an ultrasonic device capable of providing energy resources used for resonator epilation;

Fig. 7B shows a schematic drawing of an ultrasonic system for hair removal; and

Fig. 8 shows a permanent epilation effect created at the hairy side of a rabbit's ear using focal beam epilation..

15

DETAILED DESCRIPTION OF THE INVENTION

I. EXPERIMENTAL PROCEDURES

Ultrasound instruments

20 The ultrasound devices used were:

Sonicator 720 (Mettler electronics, California, USA) for frequencies of 1 MHz and 3 MHz, power output up to 2.2 W/cm^2 , pulse mode of continuous mode.

25 Focused beam ultrasound (Imasonic, Besancon, France) for frequencies of 3.9 MHz to 7.4 MHz, power up to 300 W/cm^2 .

Irradiation was performed via an aquatic solution or acoustic coupling gel or solid horn attached to the desired tissue.

EXAMPLES

Example 1 Epilation using focal ultrasonic beam

Fig. 1 (top the whole zone; bottom enlargement of irradiated zone) shows system 1 used for focal beam epilation. Focused ultrasound beam emitted from transducer 2 to skin 12. The ultrasound transducer 2 is encased by the focusing apparatus cone which includes a sheath 3 and container 4. The container fits over the sheath thread (not shown) thus by turning the container, the distance between the transducer face 14 and cover opening 13 can be continuously changed to any required length. The focused ultrasonic beam 5 in prefocal point regions propagates through the container 4 which opening 13 rests on the skin epidermis 7. The apparatus is typically set so that the beam 5 converges into a focal zone 9 at or near the opening 13 either at the apparatus-epidermis interface or in the skin itself.

The beam then widens into the post focal zone 11 and the ultrasound energy dissipates as it travels further through the dermis 6. The "destructive zone" or "effective zone" 10 is a part of the beam path proximate to the focal area 9 where the energy is concentrated enough to cause temperature elevation, denaturation and destruction of the irradiated area. The length of area 10 depends on the ultrasonic frequency. Frequencies in the MHz region, cause formation of destruction zones of few millimeters, similar to that of the hair follicle. Therefore according to this, the ultrasonic focus beam is used directly to heat and destroy the follicle papilla from outside, i.e. without using the hair as a wave guide.

10 rabbits were treated for hair removal using the above device. A small region in the ear. Each rabbit was irradiated with a focused ultrasound according to the method described above. Irradiation of each region was for 1-2 seconds. Each ear was photographed 7 months. after irradiation and the results are shown in Fig. 8.

As can be seen all hair was permanently removed from the irradiated region with virtually no re-growth. Side effects were minimal .

Example 2 Epilation using the hair as a wave guide

5 Braids of hair were fabricated by placing hairs obtained from natural hair obtained from humans in a sleeve made of rubber. The sleeve was heat-shrunk so that it tightened around the hairs which protruded out of the sleeve from both sides. Each sleeve contained about 10,000 hairs. The length of the braids, were 5 mm to 3 cm long and the diameters of the braids were 2 to 9 mm. A contact
10 *"Through Transmission"* ultrasonic measurements were executed using Ultrasonic Flaw Detector - EPOCH 3 manufactured by Panametrics, USA. Gel (Aquasonic Clear) was applied on the hair on both sides of the braid, and the ultrasonic probes, *"type P"* probes of 1/2" diameter (Harisonic. USA), were placed at the two ends of the hair braid which protruded out of the sleeve. The
15 ultrasonic wave which enters from one side was measured at the other side of the braids and the difference between the two waves was an indication of the transmittance of ultrasound by hair. A full scale signal (with amplification of 50dB) was detected under emitted signals of 1, 2.5 and 5 MHz , the frequencies performed. It is therefore clear that the hairs can serve as wave guide for
20 ultrasound transmission. This experiment clearly demonstrates that hair itself can serve as a guide for ultrasonic irradiation.

It was found that whereas attenuation of the delivered ultrasonic longitudinal wave in the hair stands at about 1 db/mm for 1 MHz and 1.35 db/mm for 5MHz (increase of 35%), the wave velocity increase from 1550 m/sec for 1
25 MHz to 2210 m/sec for 5 MHz (increase of 64%). It is known in the literature that the wave velocity of the skin is different, is about 1700 m/sec [Duck F.A. 1990 Acoustic properties of tissue at ultrasonic frequencies. In: Physical properties of tissues (Duck FA ed.), Academic Press, London p. 73-135]. It is therefore desired to work with the higher frequency here , e.g., 5 MHz, and with

dry hair which further increases the wave velocity in the hair.. The higher frequency will be accompanied by pre-treatment trimming of the hair to reduce attenuation and energy loss along the hair length when the hair is used as a wave guide. Another reason to use high frequency transducers is the rapid decrease in
5 attenuation when the wave length decreases (frequency increases) and becomes of the same order as the hair diameter. Also, when the transmitted wave has to pass from the hair to the skin, i.e., from an area of certain velocity into an area of other wave velocity, it is partially reflected and elevated the temperature at the transition location of the hair root (transition between the hair shaft and the skin
10 tissue). The elevated temperature is the most effective parameter here.

Example 3 Energy loss along the hair

In another experiment the energy loss along the hair was measured in order to determine the required irradiation intensity and hair conductivness.
15 Direct conduction construction composed of two transducers was used, the first as a transmitter that was generated using sonicator of Mettler Electronics 720, the second as a receiver connected to oscilloscope of Textronix TDS 210. Transducer's surfaces were covered by acoustic gel as described above. Initially transducer's surfaces were brought to contact with each other and peak-to-peak
20 voltage was measured with resulting voltage is 5V, which was considered as base line voltage (losses are negligible). Later transducers were connected by copper wire of 9-mm length and 0.5-mm diameter that was placed between and in perpendicular to the two transducers. The wire was placed in a drop of coupling medium at each side. The measured voltage was 20mV which means that 0.4% of
25 the acoustic energy was transferred from one transducer to the other. The experiment was carried out again under the same procedure but with one hair shaft between the transducers. Hair properties were 15-mm length and 0.12-mm diameter. The measured voltage was 7mV, which indicates that 0.14% of the emitted ultrasonic energy reached its desired location after passing in the hair

shaft. These results indicate that hair is an acceptable wave-guide when present perpendicular to the transducer.

Fig 2 shows the hair used as wave-guide from transducer or acoustic horn 20 into hair root 26 and papillae 21. Solid transducer or acoustic horn 20 is used to grasp the hair shaft 28 end for the epilation treatment. The transducer or acoustic horns a single mass with a hole or holes of a size capable of containing a hair shaft widths or is composed of two units that grasp the hair in a similar manner to tweezers. The grasping area can be also holes in horn attached to the transducer. Alternatively, the hairs may be directly attached to the transducer via acoustic coupling medium such as gel (not shown). The hair shaft 28 recedes into the skin, past the *stratum corneum* 23, epidermis 27, through the sebum partially-filled gap 22 within the follicle 29 and ends in the epidermal invagination in dermal layer 25 at the hair root 26, which covers the follicle bulbous area 24. The hair root is fed from nurturing capillaries 21 via the papilla. The ultrasonic wave emitted from transducer 20, propagates through the hair shaft and dissipates into the follicle at its inner side, where the hair root 26 is in close contact with the bulbous follicle 24 and the papillae 21. The diffusion of the ultrasonic energy at that location destroys the hair root and papillae causing epilation. The wave itself can be in the form of longitudinal or bending waves which cause thermal elevation and thermal destruction.

In an experimental example, a single hair shaft was placed at focal point of focusing transducer attached to delivery cone. The opening of the cone was covered by paraffin, on top of which a drop of acoustic gel was placed. Ends of hair shafts obtained from human arms were placed in the gel and an ultrasonic wave was emitted from transducer via aquatic medium of the cone, parafilm, and acoustic gel and hair shaft into the hair follicle and hair root. The parameters of the ultrasonic beam were frequency of 3 MHz, intensity of 3 W/mm², and duration of 120 seconds. Tweezers attached to dynamometer were used to measure the forced needed to epilate the hair. All of the non treated hair were

epilated using force of 40 to 60 grams. For the treated hair, 70% were epilated instantly, i.e., using force of less than about 2.5 grams. These results showed such irradiation parameters composed of using the hair as a wave guide for focal beam, cause epilation of at least 70% of hair.

5

Example 4 Epilation using the hair as a wave-guide

Figs. 3a to 3c show schematic drawings of another example of system used for epilation utilizing bending wave. Figure 3a shows schematic drawing of bending wave epilation effect created with two transducers 30 and 31, with their
10 respective centers *a* and *b* distance between centers *X*. Under the illustrated procedure, the distance *X* is an even number of half-wavelengths so that they are synchronized in creating maximum effect/ This causes the two waves to have the same phase and direction so that their effects are added. According to another procedure transducers 30 and 31 are placed one at each side of the hair, facing
15 each other, with an offset *X* of odd number of half-wavelengths to create the maximum effect The hair shaft 33 is pulled taut by a holding apparatus 34 such as tweezers and the interface with the transducers is via acoustic coupling medium. Holding apparatus 34 can optionally be a part of transducer or an attachment capable of emitting waves. The wave is propagated through the hair
20 shaft until reaching the hair root 35 and papilla 36 interface, effecting the destruction of this area. Mainly through torque.

An alternative method to 3a is shown in 3b using one transducer having an energy equal to the combined energy of the two transducers of drawing 3a.

The hair shaft is pulled using holding apparatus 34' and the bending wave
25 is transmitted via hair shaft 33' into the hair root 35' where it affects also the papillae 36'. The effect of the bending wave is schematically described in Fig. 3c.

A single transducer 30'' is touching the hair shaft, which is held taut by a device 34'' such as tweezers and sends a wave along the hair shaft. The subsequent forces working upon the hair root 35'' and papillae 36'' are tension

(upward arrows) and vibration (side to side arrow). These two forces cause fatigue of the hair follicle, i.e., it mechanically distract the hair-follicle connection, weaken the hair root to a point of total disconnection that allows the hair shaft to be extracted by the tweezers from the follicle itself 36" with no or
5 very little force.. The hair is used here as mechanical wave guide to create effect at desired location.

Example 5 Epilation by aggregation of blood

Fig. 4 (top- before treatment; bottom- after treatment), shows agglutination
10 of blood cells caused by ultrasound irradiation which leads to blockage of blood vessels. The signal transmitted via the hair shaft, reaches the hair root 46 and affects also blood cells 47 running in capillary 45 which enters the papillae 41. After the irradiation erythrocytes are aggregated at the narrow and curved areas of the capillary in the papillae, forming aggregates 43 that hamper the papillae
15 blood supply. Such a procedure deprives the hair root from its nutrients leading to its death. The advantage of using the hair shaft as a wave guide is that only capillaries supplying the hair roots are destroyed, while other capillaries remain unharmed According to the example shown in Fig. 6, the effect of ultrasonic waves on aggregation of erythrocytes 47 is described. Ultrasonic wave guided in
20 hair shaft and runs into the hair root 46. The energy is partially dispersed into the papillae 41 and affects the capillary 45 with its flow through erythrocytes 47. Subsequent to ultrasonic irradiation, at the bottom picture, erythrocytes 43 aggregated in the small diameter and curved capillaries. When ultrasonic wave is present for periods longer than about one minute, erythrocytes will also
25 agglutinate causing the capillaries to clog, blood flow to cease and hair root 46 and papilla 41 to die through lack of nourishment.

In an experiment irradiation of the chorio-alantoic-membrane of chick embryo was carried out with 3 MHz transducer for different durations and intensities. Irradiation for duration of more than 60-80 seconds and at intensities

higher than 1.5 W/cm^2 resulted in stasis of the blood circulation of the fine capillaries whereas the bigger diameter capillaries were not affected as determined by inspection through a binocular. The stasis was permanent, probably via formation of blood occlusion at the fine blood capillaries.

5

Example 6 Epilation by cavitation effect

Fig. 5 shows the follicle space, or gap 52 between the hair shaft 58 and follicle wall 50 which is used as cavitation space. The acoustic beam 58, created by transducer 52 and runs into the tissue. While threshold ultrasound energy required to cause cavitation in tissue itself is high, it can be lowered by
10 enriching the hair follicle by water or other acoustic coupling medium of low viscosity alone or together with helper agents such as gas enriched water, or cavitation-inducing agents such as silica particles or CCl_4 to enhance the appearance of cavitation bubbles 57 in the follicle. The cavitation, in particular
15 the transient one exploding cavitation, destroys the adjacent tissue, i.e., the follicle wall 50, hair root 56 and papilla 51.

The cavitation effect is enhanced if during cavitation the follicles are empty, for example by waxing hair prior to treatment. Fig. 6 shows the follicle cavitation in an empty follicle, i.e. the follicle lacks hair which was completely
20 removed before initiating of cavitation 67 due to the irradiation of transducer 62. In this case, the cavitation is created throughout the follicle, and since there is more space (due to lack of hair), more bubbles are created, they might be also of larger size, and their collapse directly affects the exposed papillae 61 its blood supply 65 and the follicle wall 63.

25

Example 7 Epilation by resonance force

According to yet another example shown in Fig. 7A, the resonator epilation embodiment is described. The resonator box 74 is connected to the transducer 72. The resonator can be for example a hollow cylinder filled with a

fluid 77 such as water, having good acoustic-wave transmission properties. Preferably the acoustic impedance Z of the liquid 77 is intermediate to that of transducer 72 and hair shaft 78. The size of the resonator, between transducer 72 and end of hair shaft 78 is chosen in such way that the wave is amplified
5 maximally in order to cause oscillation of the wall of the resonator, which is present opposite the transducer. This wall is a thin elastic membrane 75 which parameters are given below. To this membrane hair shaft 78 is fastened either mechanically or with glue to a holder 76. The hair is slightly stretched in order to have good transmission of the stretching wave created by the oscillating
10 movement of membrane 75, so it is stretched and relaxed with membrane oscillation. The wave propagate through the hair shaft 78 and affect the hair root area 79 by pull and push movements that causes periodical stress. As loading is applied during many cycles, the root reaches a state of fatigue and detachment of the follicle-root zone, after which hair is freely removed.

15 The damage in the hair depends primarily on the wave frequency, i.e., on the amount of stretching/relaxation cycles which reaches the follicle and on the amplitude of movement. Wave with higher amplitude will cause a stronger relaxation of hair and this will reduce average hair loading.

A calculation can provide the intensity needed to create movement of the
20 membrane close to or at its own resonance frequency, which should fit to the frequency of ultrasonic wave. For instance, to create vibration of membrane with amplitude of 1 mm, using aluminum round membrane with diameter of 50 mm and thickness 0.5 mm acoustic pressure of 1.1756 atm or Intensity of 1.43 W/cm^2 are needed.

25 The space between membrane 75, holder 76 and the skin surface is in fact composed of air. Alternatively, or in addition, the space can be maintained using a suitable spacer (not shown in the Fig.) composed of a non-conducting or a non-ultrasonic conducting component.

The formulas used for calculation is:

$$Pa = 64DA/R^4$$

$$D = Eh^3/12(1-\nu^2)$$

Pa – acoustic pressure, *R* – radius of membrane, *E* – Young's modulus

h – thickness of membrane, *ν* – Poisson ratio, *A* – vibration amplitude

E = 68Gpa, *ν* = 0.334, *R* = 25mm, *h* = 0.5mm, *A* = 1mm

2 Increase of membrane radius leads to significant decrease of acoustic pressure, increase of membrane thickness leads to significant increase of acoustic pressure, usage of material with lower Young's modulus leads to proportional decrease of acoustic pressure.

5 The ultrasonic parameters to perform this embodiment, depend on the material of the oscillating membrane which produces the resonance energy. This data are for Aluminum are as follows:

Frequency: 1 kHz to 5 MHz preferably 1 MHz to 5 MHz, most preferably 2 MHz to 5 MHz.

10 Intensity: 0.3 W/cm² to 50 W/cm², preferably 0.5 W/cm² to 10 W/cm², most preferably 1 W/cm² to 5 W/cm²

Duration: 0.01 second to 10 minutes, preferably 1 second to 5 minutes, most preferably few seconds.

15 **Example 8 System for hair removal**

Fig. 7B shows a schematic illustration of a system for ultrasonic removal of hair. The system is schematically composed of two main parts: the first is a signal generator 102 comprising of a voltage source 104, a frequency converter 106, a signal amplifier 108.

20 The second part of the system which can be constructed as a single unit or operated as separate independent units is an ultrasonic treatment unit 110.

The ultrasonic treatment unit 110 may also include the following components: the transducer 112, which produces ultrasonic vibration, positioned in the treatment part 110. The transducer horn 114 amplifies and transmits the

vibrations to the removable tip 116, which further amplifies the vibration, for instance the resonator described in Fig. 7A. Tip 116 also acts as a holder for a hair gripper element 118, which is a part intended to grip the hair and may have any configuration known in the art. However the gripper element can be also
5 connected to other components of the system, as long as they do not interfere with its hair gripping properties. These several parts 112, 114, 116 and 118 can be also arranged as one integral unit.

Sensor 120 monitors the ultrasonic converter and through a feedback line 124 maintains optimal driving conditions from the voltage source 104,
10 frequency converter 106 and signal amplification 108 units. Such feedback is needed in particular for safety reasons, but might be also used for the regular course of operation.

Additionally, the hair gripper 118 which is also the ultrasonic horn tip should preferably be kept a consistent and predetermined distance from the skin
15 by means of a spacer device (not shown). This spacer device will act as a protective mechanism, avoiding contact between irradiating elements and the skin, as well as improve energy transfer from transducer to hair.

CLAIMS:

1. A cosmetic method for removal of hair from a desired skin zone comprising applying to said skin zone an ultrasonic irradiation having such
5 parameters so as to destroy, decrease growth or deteriorate the hair shaft, hair root, hair follicle, hair papillae or to cause cessation or decrease of the blood supply to the hair root or hair papillae.
2. A method according to Claim 1, comprising irradiating said desired zone by a focused ultrasonic beam having such parameters so as to cause destruction,
10 decrease of growth or deterioration of the hair shaft, hair follicle, hair root, hair papillae or to cessation or decrease of the blood supply to the hair root or hair papillae.
3. A method according to Claim 2, wherein the ultrasound irradiation has the frequency of 10 kHz to 50 MHz, intensity of 5 W/cm^2 to 750 W/cm^2 and duration
15 of 1 millisecond to 10 seconds.
4. A method according to Claim 3, wherein the ultrasound irradiation has the frequency of 1 MHz to 10 MHz, intensity of 30 W/cm^2 to 500 W/cm^2 and duration of 0.01 second to 2 seconds.
5. A method according to claim 4, wherein the ultrasound irradiation has the
20 frequency of 3 MHz to 7 MHz, intensity of 100 W/cm^2 to 300 W/cm^2 and duration of 0.1 second to 0.5 seconds.
6. A method according to Claim 1, comprising irradiating the desired skin zone with an ultrasonic irradiation having such parameters so as to cause a cavitation affect within the hair follicle leading to destruction, decrease of growth
25 or deterioration of the hair shaft, hair follicle, hair root, hair papillae or to cessation or decrease of the blood supply to the hair root or hair papillae.
7. A method according to Claim 6, wherein the cavitation effect is carried out on untreated skin.

8. A method according to Claim 6, comprising immersing the desired skin zone, prior to or simultaneously with irradiation, in an ultrasonic coupling medium capable of entering the hair follicles.
9. A method according to Claim 8, wherein the coupling medium is enriched by cavitation enhancing agents for facilitation of cavitation.
10. A method according to claim 9, wherein the cavitation enhancing agents are dissolved gases.
11. A method according to Claim 10, wherein the gas is CO₂.
12. A method according to Claim 10, wherein the cavitation enhancing agent is capable of increasing the gas pressure of the collapsing bubbles.
13. A method according to Claims 8 to 12, wherein prior to cavitation the hair in the desired zone is mechanically plucked out and cavitation takes place in empty hair zones.
14. A method according to Claim 6, wherein the ultrasound irradiation has the frequency of 1 KHz to 5 MHz, intensity of 0.3 W/cm² to 500 W/cm² and duration of 0.01 second to 10 minutes.
15. A method according to Claim 14, wherein the ultrasound irradiation has the frequency of 10 KHz to 2 MHz, intensity of 0.5 W/cm² to 50 W/cm² and duration of 1 seconds to 5 minutes.
16. A method according to Claim 13, wherein the ultrasound irradiation has the frequency of 100 KHz to 1 MHz, intensity of 1 W/cm² to 10 W/cm² and duration of less than 7 sec.
17. A method according to Claim 1, wherein the hair shaft serves as wave guide of the ultrasonic irradiation, transferring the irradiation through the hair shaft into the hair root, the hair follicle, the hair papillae or to the blood supply to the hair papillae.
18. A method according to Claim 17, wherein the ultrasonic irradiation is in the form of at least one of the following waves:
- (i) longitudinal waves;

- 28 -

- (ii) shear waves;
- (iii) bending waves; and
- (iv) torsion waves.

19. A method according to Claims 17 to 18 used for longitudinal waves, shear
5 waves, bending waves and torsion waves wherein the ultrasound irradiation has
the frequency of 1 MHz to 50 MHz, 0.5 MHz to 25 MHz, 0.25 MHz to 12 MHz
or 0.25 MHz to 12 MHz, respectively; intensity of 0.5 W/cm^2 to 500 W/cm^2 and
duration of 0.01 second to 10 minutes.

20. A method according to Claim 19, wherein the ultrasound irradiation used
10 for longitudinal waves, shear waves, bending waves and torsion waves has the
frequency of 10 MHz to 30 MHz, 5 MHz to 15 MHz, 2 MHz to 7 MHz, 2 MHz
to 7 MHz, respectively; intensity of 3.5 W/cm^2 to 50 W/cm^2 and duration of 1
second to 5 minutes.

21. A method according to Claim 20, wherein the ultrasound irradiation used
15 for longitudinal waves, shear waves, bending waves and torsion waves has the
frequency of 20 MHz to 25 MHz, 10 MHz to 12 MHz, 5 MHz to 6 MHz, 5 MHz
to 6 MHz, respectively; intensity of 10 W/cm^2 to 20 W/cm^2 and duration of
less than 7secs.

22. A method according to Claim 1, comprising irradiating the desired skin
20 with ultrasonic irradiation via a resonator, leading to destruction, decrease of
growth or deterioration of the hair shaft, hair follicle, hair root, hair papillae or to
cessation or decrease of the blood supply to the hair root or hair papillae.

23. A method according to Claim 22, wherein the ultrasound irradiation has
the frequency of 1 kHz to 5 MHz, intensity of 0.3 W/cm^2 to 50 W/cm^2 and
25 duration of 10 millisecond to 10 minutes.

24. A method according to Claim 23, wherein the ultrasound irradiation has
the frequency of 1 MHz to 5 MHz, intensity of 0.5 W/cm^2 to 10 W/cm^2 and
duration of 1 seconds to 5 minutes.

25. A method according to Claim 24, wherein the ultrasound irradiation has the frequency of 2 MHz to 5 MHz, intensity of 1 W/cm² to 5 W/cm² and duration of less than 7 seconds to .
26. A method according to Claim 1, comprising irradiating the skin zone in
5 the presence of agents capable of degeneration of hair, hair follicle, hair roots or hair follicles.
27. A method according to Claim 26, wherein said degenerative agents are sebum naturally present in the hair follicle.
28. A method according to Claim 26, wherein said degenerative agents are
10 selected from the following groups:
- (i) sonosensitizable agents capable of undergoing oxidative or exothermic reactions upon ultrasonic irradiation or exposure to light;
 - (ii) oil capable of causing pore clogging;
 - 15 (iii) substances capable of modulating the cell cycle of the root, papillae or blood vessel cell; and
 - (iv) androgenic hormones.
29. A method according to Claim 28, wherein the sonosensitizable agents are selected from: gallium porphyrins, dimethylsulfoxide, dimethylforma and
20 adramycin, NaN₃, nitrocellulose, nitrated metallorganic, oxidation of carbohydrate compounds.
30. A method according to Claim 29, wherein the sonosensitizable components are accompanied by agents capable of facilitating the oxidative reactions selected from the group consisting of: O₂, chloride, kalium and
25 permanganate.
31. A method according to Claim 28 wherein the substances capable of effecting the cell's growth cycle are cytokines.
32. A method according to Claim 28, wherein the androgenic hormones are dihydrotestosterone or 5-alpha-reductase.

33. A method according to Claim 28, comprising: plucking the hairs out of their follicle in the presence of a liquid solution containing the degenerative agents.

34. A method according to Claim 28, comprising:

- 5 (i) exposing the skin to a first irradiate ultrasound stimulus being such as to cause transient enlargement of the openings of the hair follicles and clearing the follicle zone without causing irreversible damage to the skin; the opening being of a size allowing entry therethrough, of said degenerative agents;
- 10 (ii) within a time period where at least a portion of said openings remain open, exposing the skin to a second driving ultrasound stimuli; said second ultrasound stimulus being effective in driving at least part of said degenerative agents through said opening without causing any irreversible damage to the skin, thereby
- 15 causing entry of said agents to the follicles..

35. A method according to Claim 34, wherein the first and second stimulus are applied simultaneously.

36. A method according to Claim 34, wherein the interval between the first and second stimulus is up to 15 minutes.

20 37. A method according to Claim 34, wherein the first stimulus has the frequency of 20 kHz to 3 MHz, duration of 0.01 sec. to 20 min. and intensity of 0.1 to 500 W/cm².

38. A method according to Claim 37, wherein the first stimulus has the frequency of 100 kHz to 1.5 MHz, duration of 0.1 sec. to 30 sec. and intensity of

25 0.5 – 100 W/cm².

39. A method according to Claim 38, where the first stimulus has the frequency of 500 kHz to 1 MHz, duration of less than 1 sec. and intensity of 3 – 50 W/cm².

40. A method according to Claim 34, where the second stimulus has the frequency of 20 kHz to 50 MHz, duration of 0.01 sec. to 20 min. and intensity of 0.1 – 10 W/cm².
41. A method according to Claim 40, wherein the second stimulus has the
5 frequency of 2 – 15 MHz, duration of 0.1 – 5 min. and intensity of 0.1 – 10 W/cm².
42. A method according to Claim 41 wherein the second stimulus has the frequency of 3 – 5 MHz, duration of 5 – 10 sec. and intensity of 0.5 – 5 W/cm².
43. A method according to Claim 1, wherein the ultrasonic irradiation has
10 such parameters so as to cause aggregation of blood cells in the blood vessels nurturing the hair root or hair papillae.
44. A method according to Claim 43, wherein the ultrasonic irradiation has the following parameters:
Frequency 100 KHz to 15 MHz, intensity 0.1- 50 W/cm², duration 1 sec. to 10
15 mins.
45. A method according to Claim 44, wherein the ultrasonic irradiation has the following parameters:
Frequency 500 kHz to 10 MHz, intensity 0.5 W/cm² to 10 W/cm², duration 10
sec. to 5 mins.
- 20 46. A method according to Claim 45, wherein the ultrasonic irradiation has the following parameters:
Frequency 1 kHz to 5 MHz, intensity 1 W/cm² to 3 W/cm², duration 30 sec. to 2
mins.
47. A method according to Claims 43 to 46, wherein the ultrasonic irradiation
25 is a focused ultrasonic beam.
48. A device for removing hair for use in any of the methods of Claims 1 to 46, or a combination of one or more of the methods of Claims 1 to 47.
49. A system for removing hair comprising the device of Claim 48.
50. A device substantially as hereinbefore described..

51. A system substantially as hereinbefore described.

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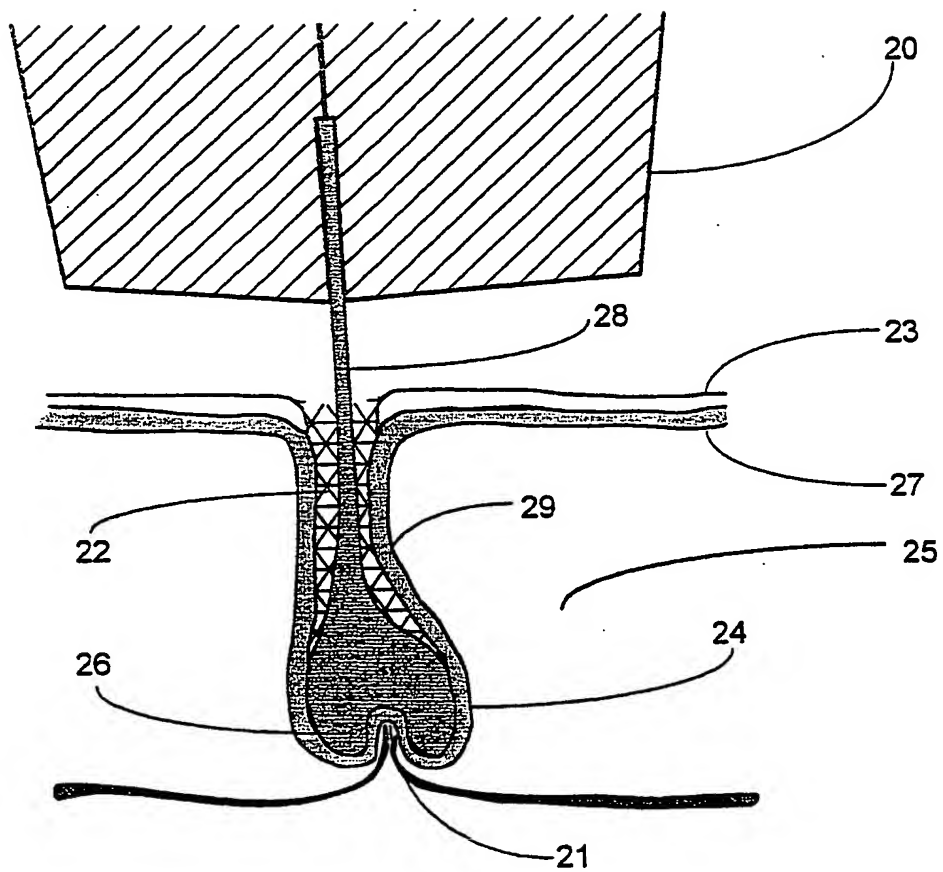


Fig. 2

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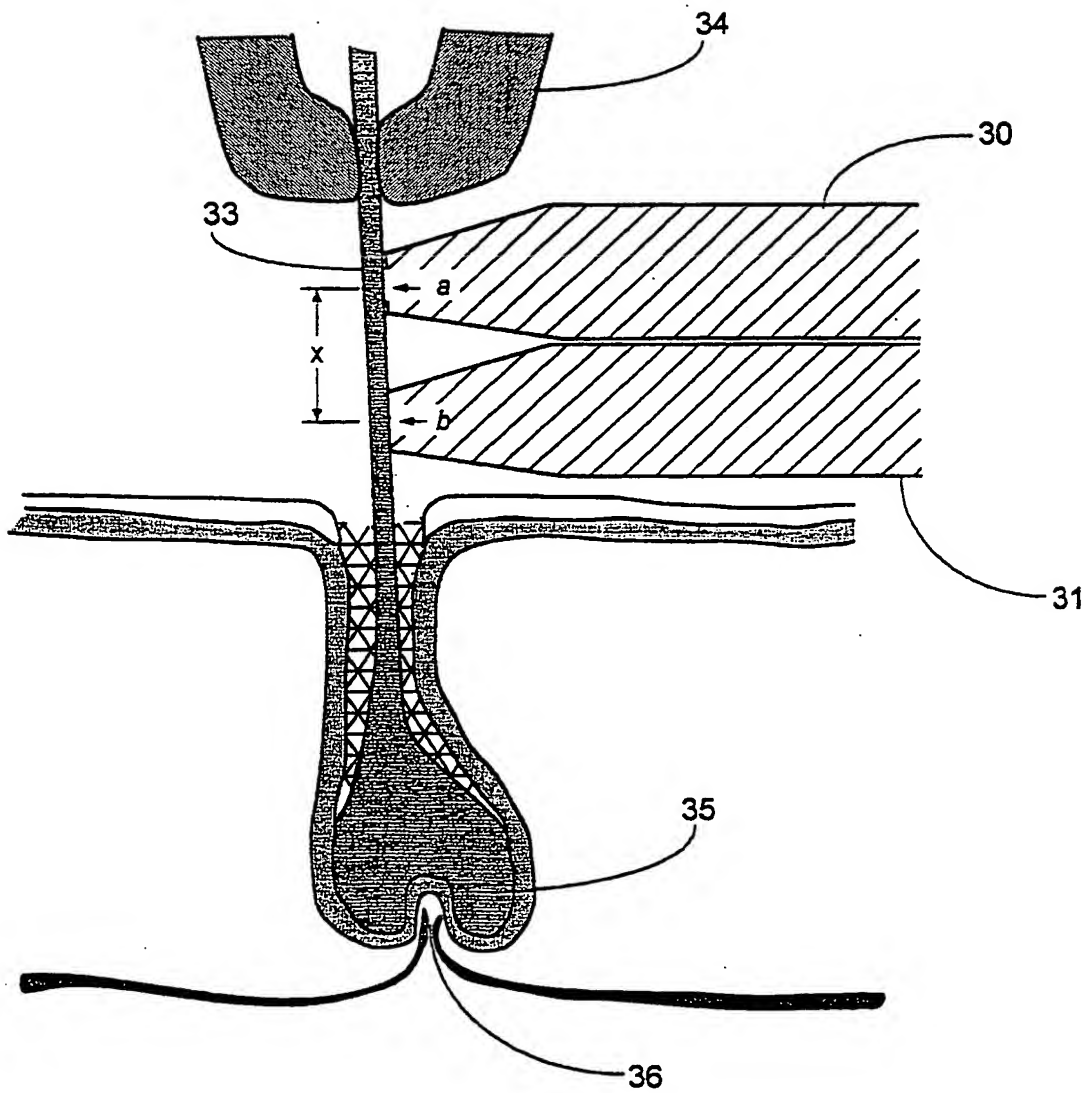


Fig. 3a

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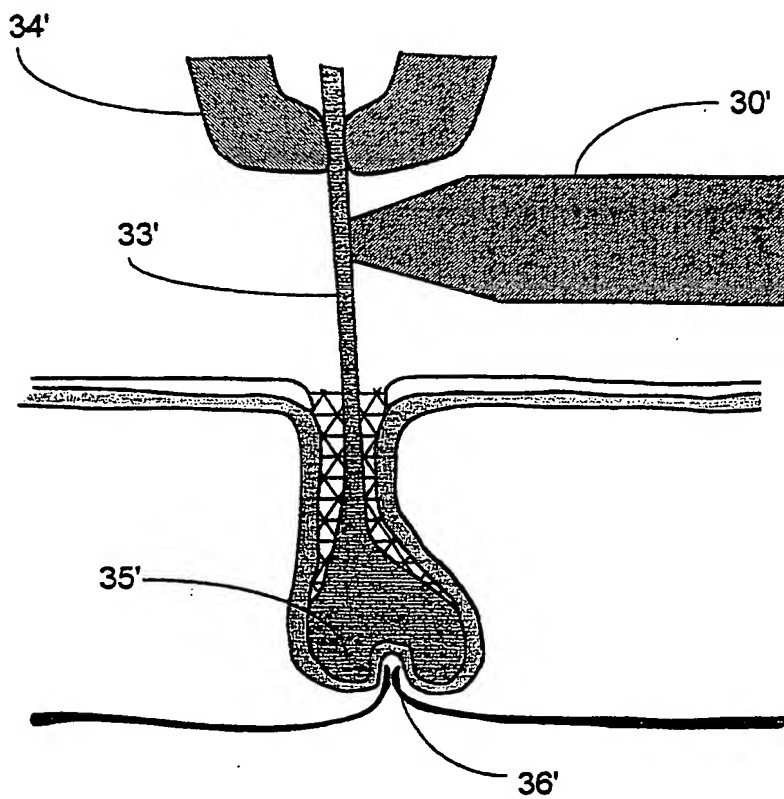


Fig. 3b

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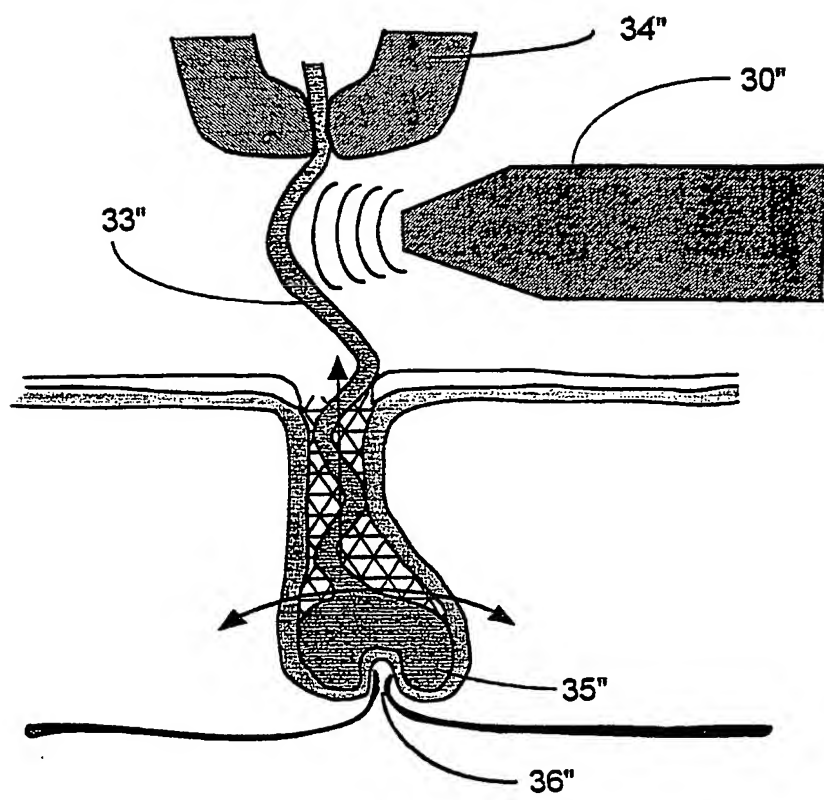


Fig. 3c

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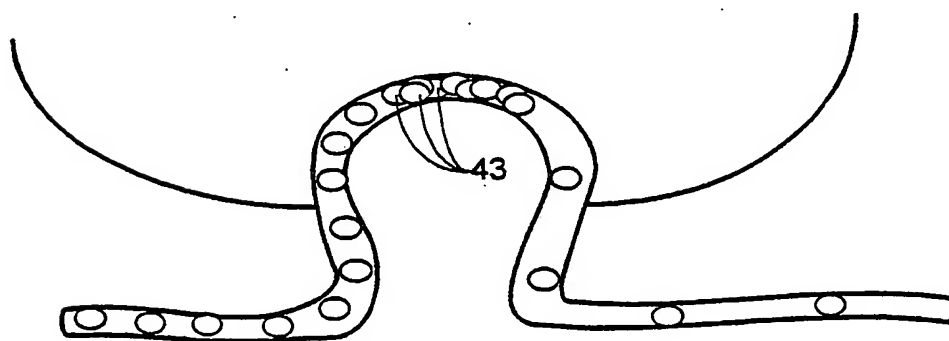
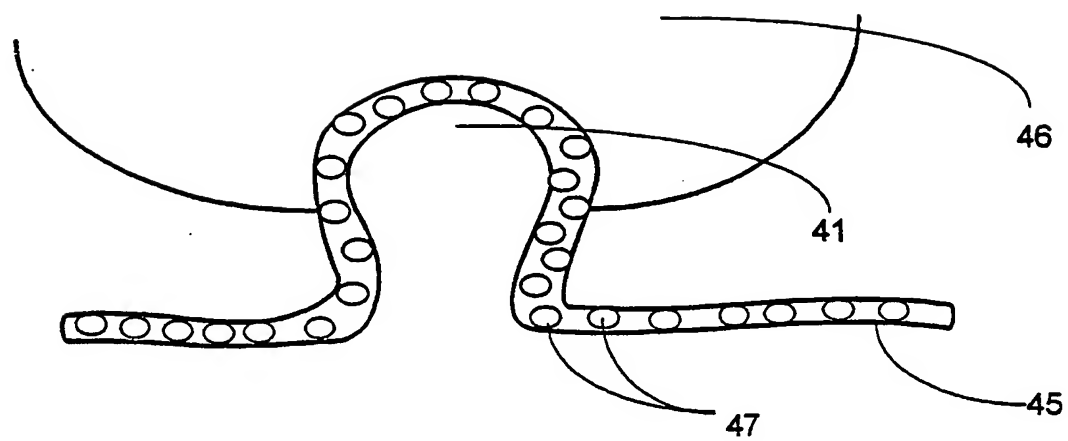


Fig. 4

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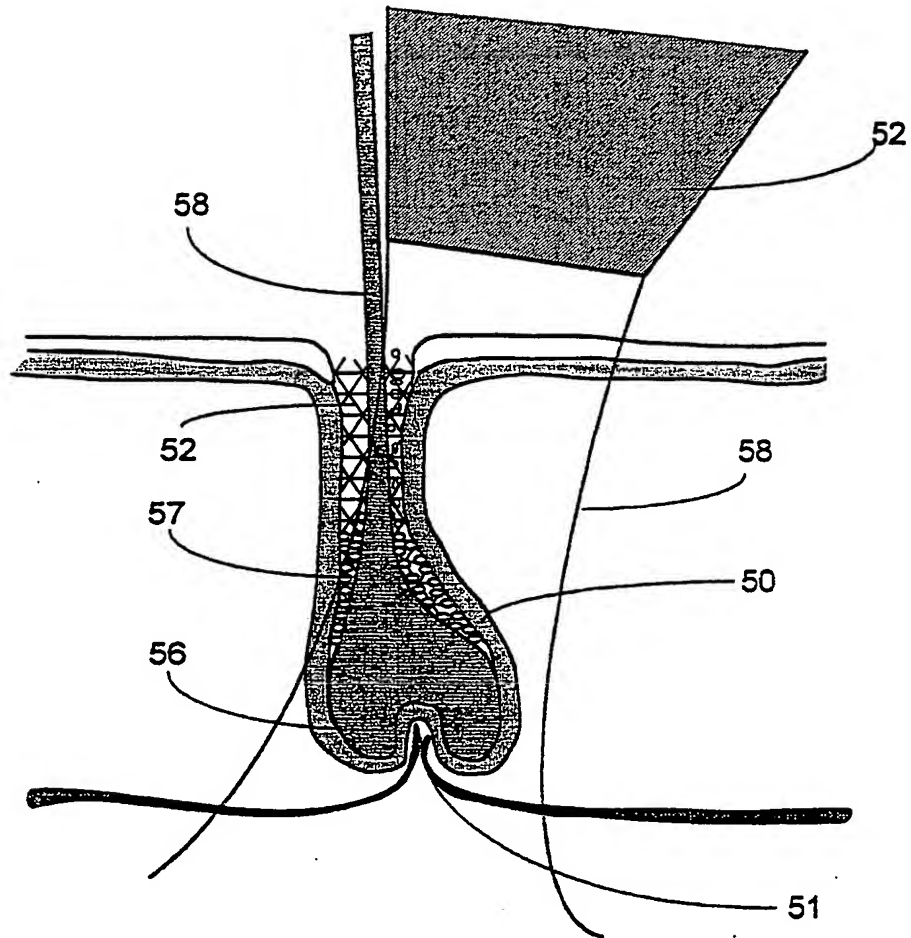


Fig. 5

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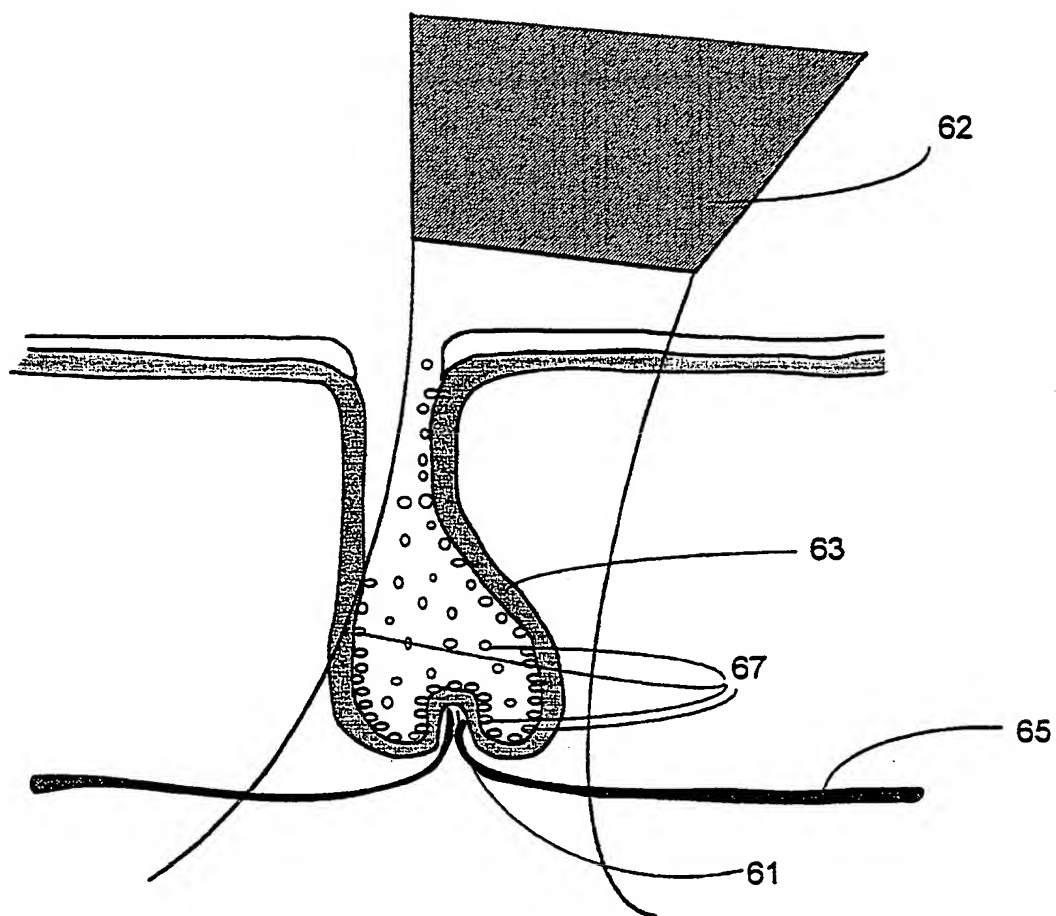


Fig. 6

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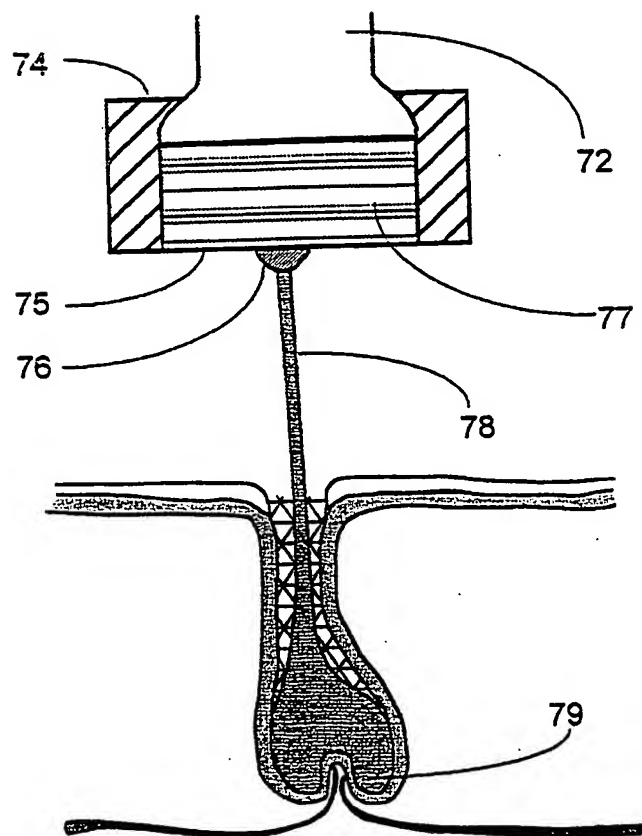


Fig. 7a

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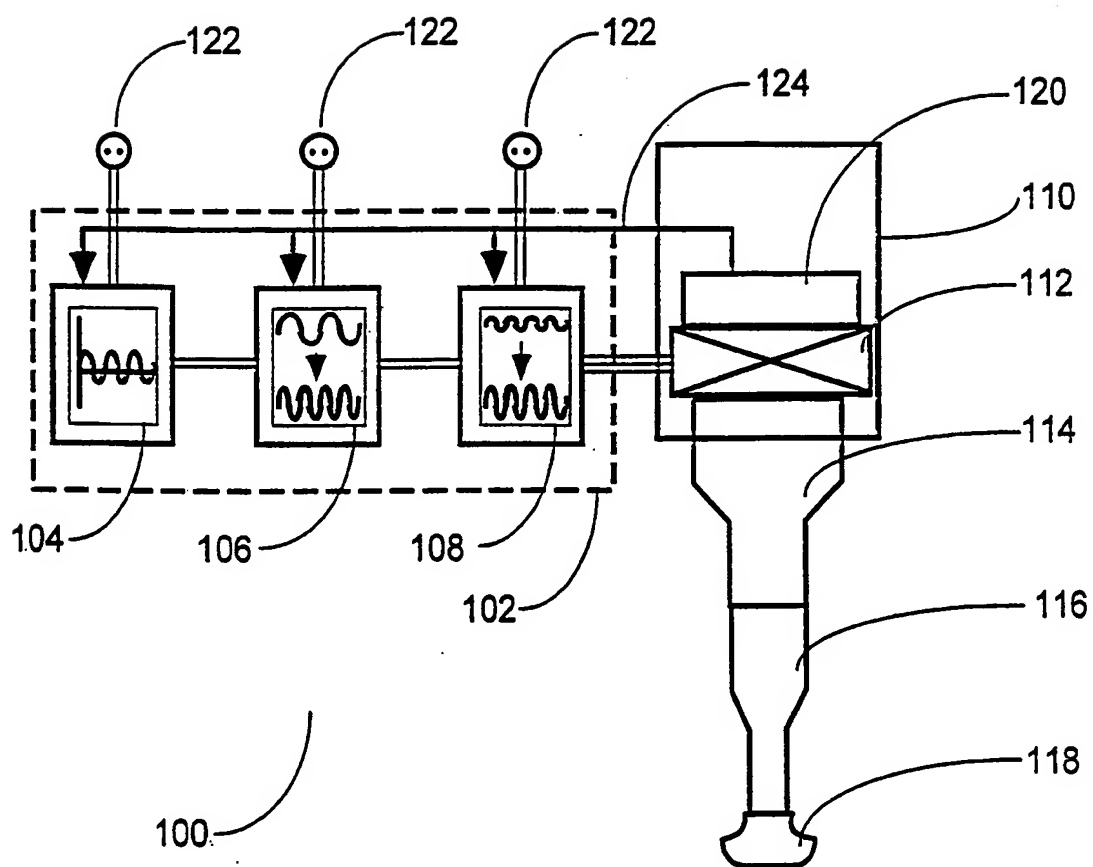


Fig. 7b

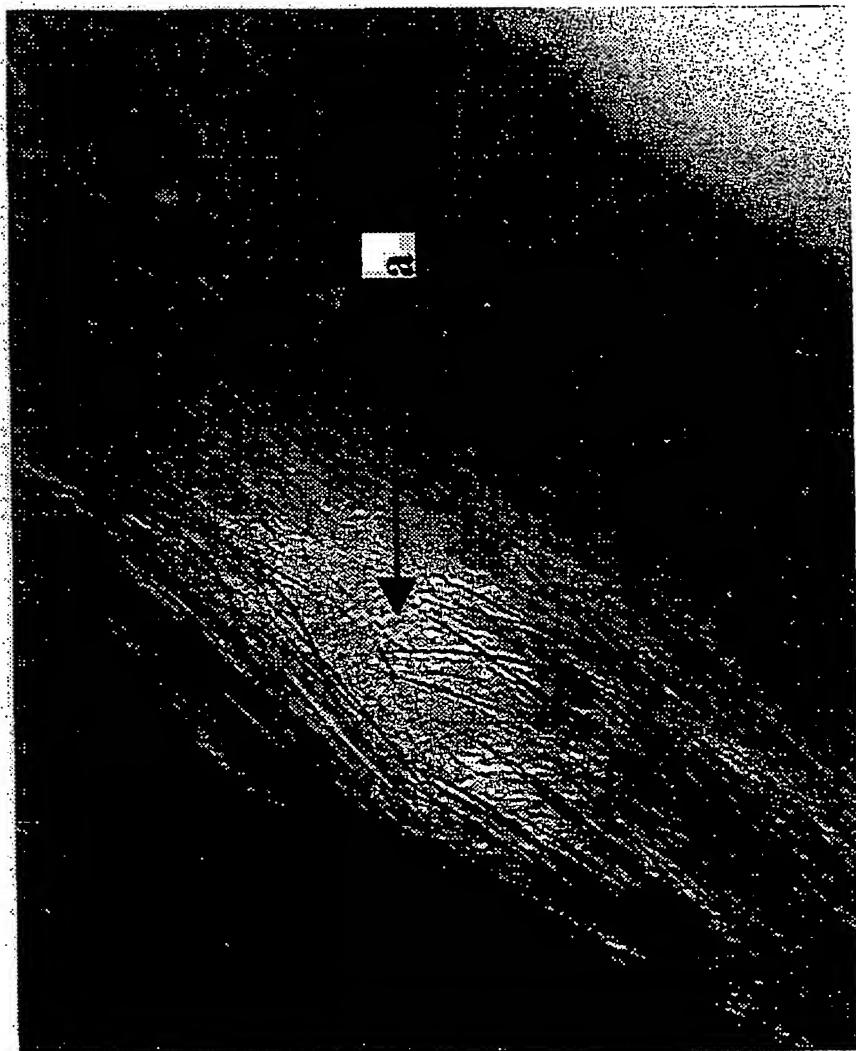


Fig. 8

INTERNATIONAL SEARCH REPORT

Inter. Appl. No.
PCT/IL 99/00533

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61N7/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61N A45D A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 98 32379 A (TECHNION RES & DEV FOUNDATION ;IGER YONI (IL); KIMMEL EITAN (IL)) 30 July 1998 (1998-07-30) cited in the application page 3, line 19 - line 20 page 15, line 20 - line 26	1,2, 48-51
Y	EP 0 824 003 A (TAPPER ROBERT) 18 February 1998 (1998-02-18) column 8, line 26 - line 56	26,27 3,6,17, 22
A	EP 0 860 123 A (THERMOLASE CORP) 26 August 1998 (1998-08-26) page 3, line 2 - line 7	26,27 48-51

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

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Date of the actual completion of the international search

17 January 2000

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL 99/ 00533

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 43-47
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Claims 1,2,6,17,22,48-51, containing a method for deterioration of blood supply by clogging blood vessels, were searched partially according to rule 39.1 (iv).

Continuation of Box I.1

Claims Nos.: 43-47

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IL 99/00533

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9832379 A	30-07-1998	AU 5234698 A	18-08-1998
EP 0824003 A	18-02-1998	JP 10146392 A	02-06-1998
EP 0860123 A	26-08-1998	US 5226907 A	13-07-1993
		AT 170056 T	15-09-1998
		DE 69226779 D	01-10-1998
		DE 69226779 T	25-03-1999
		DE 601130 T	07-11-1996
		EP 0601130 A	15-06-1994
		ES 2124265 T	01-02-1999
		GR 96300045 T	31-08-1996
		JP 2617084 B	04-06-1997
		JP 6509734 T	02-11-1994
		SG 49083 A	18-05-1998
		US 5425728 A	20-06-1995
		WO 9308715 A	13-05-1993
		US 5423803 A	13-06-1995
		US 5713845 A	03-02-1998
		US 5817089 A	06-10-1998
		US 5752948 A	19-05-1998
		US 5752949 A	19-05-1998
		US 5925035 A	20-07-1999
		US 5871480 A	16-02-1999

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